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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/095,385	06/10/98	MORRISON S	30435.450601

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EXAMINER	
ZEMAN, M	
ART UNIT	**PAPER NUMBER**
1643	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/095,385	Applicant(s) MORRISON ET AL.	
	Examiner Mary K Zeman	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *15 October 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *16-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☒ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6,7,8* .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that there is no serious burden upon the examiner to search all groups; and that all the claims are linked by a common inventive concept. This is not found completely persuasive for the reasons set forth below.

Applicant's arguments are persuasive between Group I and Group II. It appears that the only methods which would actually produce the claimed antibodies are the methods of Group I. However, Applicant's arguments are not persuasive in regards to Groups III and IV. As set forth in the restriction requirement, Group I is separate and distinct from Groups III and IV as they are differing methods having differing steps and intended outcomes. These methods require different types of searches, as methods of treating a disease would not necessarily illuminate the subject matter of producing recombinant immunoglobulins. This is evidenced, in part, by the separate classifications of the two inventions. Between the inventions of Group III and Group IV there are also differences which would require differing search and consideration issues. Methods of preventing an infection and methods of treating an existing infection differ in their intended patient groups, and the intended outcomes. Differing types of evidence are required, and different types of literature searching are also required.

In summary, Claims 1-15, representing Groups I and II will be examined in this action, and Claims 16-27 are withdrawn from consideration as being drawn to a non-elected invention.

Priority

Priority under 35 U.S.C. 119(e) to provisional application 60/050,969, filed 6/19/97, is acknowledged.

Drawings

Applicant's preliminary amendment to the specification clarifying the number and arrangement of the drawings has been entered.

Claim Rejections - 35 USC § 112

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method of producing secretory Ig molecules, however, no steps are present wherein the transfected cell is cultured such that any secretory Ig molecules would be produced. As such, the method is indefinite.

Also in claim 1, one "cell" is transfected, and results in the production of "cells". This does not appear to be logical. Either a population of cells is transfected, or else only one cell is produced.

Claim 3 recites the limitation "sIg" in reference to claim 2, neither claim 1 or claim 2 set forth sIg. There is insufficient antecedent basis for this limitation in the claim.

In claims 4 and 5 the secretory Ig and SC are either from the same or different species. Species of what?

The metes and bounds of the term "congener" in claim 6 is unclear. It is unclear whether this term simply denotes the complementary sequence, or whether other changes are intended to fall within the scope of the claim. Also, the limits of how much the sequence can be changed and still fall within the scope of the claim are entirely unclear.

Claims 12 and 13 recites the limitation "Ig molecule" in reference to claim 1, however claim 1 only refers to a cell producing "an Ig". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-5, 7, 9-12, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Weltzin (US Patent 5,534,411).

The claims are drawn to methods of producing a secretory Ig from cells producing both Ig and secretory component, and Ig molecules so produced. IgA is a preferred Ig, and a mammalian myeloma cell is one embodiment.

Weltzin (US Patent 5,534,411) discloses such a method at column 11. "In another method, the IgA-secreting hybridoma cells are transfected with an expression vector containing the cDNA for secretory component. The resulting cells produce IgA-secretory component complexes." Weltzin discloses methods of culturing IgA secreting hybridomas, methods of collecting the IgA and methods of purifying the IgA. Weltzin also discloses pharmaceutical preparations of the antibodies with a pharmaceutically acceptable carrier, and/or an adjuvant. (See Example 3) The preferred antibody of Weltzin is a monoclonal IgA produced by a mouse hybridoma, and is specific for RSV antigens (HNK20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weltzin (US Patent 5,534,411), as applied to claims 1-5, 7, 9-12 and 14-15 above, in view of Morrison (WO 89/07142 #9 PTO-1449) and Krajci (Biochem. Biophys. Res. Comm. 1989 158 (3) 783-789).

As set forth above, Weltzin (US Patent 5,534,411) discloses such a method at column 11. "In another method, the IgA-secreting hybridoma cells are transfected with an expression vector containing the cDNA for secretory component. The resulting cells produce IgA-secretory component complexes." Weltzin discloses methods of culturing IgA secreting hybridomas, methods of collecting the IgA and methods of purifying the IgA. Weltzin also discloses pharmaceutical preparations of the antibodies with a pharmaceutically acceptable carrier, and/or an adjuvant. (See Example 3) The preferred antibody of Weltzin is a monoclonal IgA produced by a mouse hybridoma, and is specific for RSV antigens (HNK20). Weltzin discusses modifying the domains of the mouse monoclonal to replace the mouse domains with human sequences at column 11, lines 28-38. Weltzin does not disclose particular methods for carrying out such a modification, nor does Weltzin set forth a sequence for the secretory component.

Morrison (WO 89/07142) discloses the specific domain modification of immunoglobulins set forth in the specification. Morrison sets forth that this method is

particularly useful for creating recombinant immunoglobulins which have human or humanized domain sequences, as these modified immunoglobulins are more useful in treatment applications.

Krajci (Biochem. Biophys. Res. Comm. 1989 158 (3) 783-789) discloses sequences of the secretory component.

Taken together, the instant invention appears to be the same or slightly different from the prior art of producing recombinant immunoglobulins comprising secretory component. Weltzin discloses the claimed methods of transfecting Ig producing cells with a vector comprising the secretory component sequence, Krajci discloses a specific secretory component sequence, and Morrison sets forth methods for modification of the domains of an immunoglobulin, as claimed.

One of ordinary skill in the art at the time the invention was made would have been motivated to select and evaluate the domain modification strategy of Morrison, as it allows for the production of human or humanized recombinant immunoglobulins, which are more useful for in vivo applications. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The

examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner, can be reached on (703) 308-1032.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz
December 2, 1999

DONNA WORTMAN
PRIMARY EXAMINER